

Medication Guide content or format requirement, except those requirements in § 208.20 (a)(2) and (a)(6), on the basis that the requirement is inapplicable, unnecessary, or contrary to patients' best interests. Requests from applicants should be submitted to the director of the FDA division responsible for reviewing the marketing application for the drug product, or for a biological product, to the application division in the office with product responsibility.

(b) If the licensed practitioner who prescribes a drug product subject to this part determines that it is not in a particular patient's best interest to receive a Medication Guide because of significant concerns about the effect of a Medication Guide, the licensed practitioner may direct that the Medication Guide not be provided to the particular patient. However, the authorized dispenser of a prescription drug product subject to this part shall provide a Medication Guide to any patient who requests information when the drug product is dispensed regardless of any such direction by the licensed practitioner.

## **PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL**

Sec.

210.1 Status of current good manufacturing practice regulations.

210.2 Applicability of current good manufacturing practice regulations.

210.3 Definitions.

AUTHORITY: 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374.

SOURCE: 43 FR 45076, Sept. 29, 1978, unless otherwise noted.

### **§ 210.1 Status of current good manufacturing practice regulations.**

(a) The regulations set forth in this part and in parts 211 through 226 of this chapter contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength

and meets the quality and purity characteristics that it purports or is represented to possess.

(b) The failure to comply with any regulation set forth in this part and in parts 211 through 226 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action.

### **§ 210.2 Applicability of current good manufacturing practice regulations.**

(a) The regulations in this part and in parts 211 through 226 of this chapter as they may pertain to a drug and in parts 600 through 680 of this chapter as they may pertain to a biological product for human use, shall be considered to supplement, not supersede, each other, unless the regulations explicitly provide otherwise. In the event that it is impossible to comply with all applicable regulations in these parts, the regulations specifically applicable to the drug in question shall supersede the more general.

(b) If a person engages in only some operations subject to the regulations in this part and in parts 211 through 226 and parts 600 through 680 of this chapter, and not in others, that person need only comply with those regulations applicable to the operations in which he or she is engaged.

### **§ 210.3 Definitions.**

(a) The definitions and interpretations contained in section 201 of the act shall be applicable to such terms when used in this part and in parts 211 through 226 of this chapter.

(b) The following definitions of terms apply to this part and to parts 211 through 226 of this chapter.

(1) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 *et seq.*).

(2) *Batch* means a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(3) *Component* means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.

(4) *Drug product* means a finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

(5) *Fiber* means any particulate contaminant with a length at least three times greater than its width.

(6) *Non-fiber-releasing filter* means any filter, which after any appropriate pretreatment such as washing or flushing, will not release fibers into the component or drug product that is being filtered. All filters composed of asbestos are deemed to be fiber-releasing filters.

(7) *Active ingredient* means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

(8) *Inactive ingredient* means any component other than an *active ingredient*.

(9) *In-process material* means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the drug product.

(10) *Lot* means a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits; or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.

(11) *Lot number, control number, or batch number* means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the

manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.

(12) *Manufacture, processing, packing, or holding of a drug product* includes packaging and labeling operations, testing, and quality control of drug products.

(13) The term *medicated feed* means any Type B or Type C medicated feed as defined in §558.3 of this chapter. The feed contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated feeds is subject to the requirements of part 225 of this chapter.

(14) The term *medicated premix* means a Type A medicated article as defined in §558.3 of this chapter. The article contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated premixes is subject to the requirements of part 226 of this chapter.

(15) *Quality control unit* means any person or organizational element designated by the firm to be responsible for the duties relating to quality control.

(16) *Strength* means:

(i) The concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis), and/or

(ii) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard).

(17) *Theoretical yield* means the quantity that would be produced at any appropriate phase of manufacture, processing, or packing of a particular drug product, based upon the quantity of components to be used, in the absence of any loss or error in actual production.

(18) *Actual yield* means the quantity that is actually produced at any appropriate phase of manufacture, processing, or packing of a particular drug product.

(19) *Percentage of theoretical yield* means the ratio of the actual yield (at any appropriate phase of manufacture, processing, or packing of a particular

drug product) to the theoretical yield (at the same phase), stated as a percentage.

(20) *Acceptance criteria* means the product specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan, that are necessary for making a decision to accept or reject a lot or batch (or any other convenient subgroups of manufactured units).

(21) *Representative sample* means a sample that consists of a number of units that are drawn based on rational criteria such as random sampling and intended to assure that the sample accurately portrays the material being sampled.

(22) *Gang-printed labeling* means labeling derived from a sheet of material on which more than one item of labeling is printed.

[43 FR 45076, Sept. 29, 1978, as amended at 51 FR 7389, Mar. 3, 1986; 58 FR 41353, Aug. 3, 1993]

## PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

### Subpart A—General Provisions

Sec.

211.1 Scope.

211.3 Definitions.

### Subpart B—Organization and Personnel

211.22 Responsibilities of quality control unit.

211.25 Personnel qualifications.

211.28 Personnel responsibilities.

211.34 Consultants.

### Subpart C—Buildings and Facilities

211.42 Design and construction features.

211.44 Lighting.

211.46 Ventilation, air filtration, air heating and cooling.

211.48 Plumbing.

211.50 Sewage and refuse.

211.52 Washing and toilet facilities.

211.56 Sanitation.

211.58 Maintenance.

### Subpart D—Equipment

211.63 Equipment design, size, and location.

211.65 Equipment construction.

211.67 Equipment cleaning and maintenance.

211.68 Automatic, mechanical, and electronic equipment.

211.72 Filters.

### Subpart E—Control of Components and Drug Product Containers and Closures

211.80 General requirements.

211.82 Receipt and storage of untested components, drug product containers, and closures.

211.84 Testing and approval or rejection of components, drug product containers, and closures.

211.86 Use of approved components, drug product containers, and closures.

211.87 Retesting of approved components, drug product containers, and closures.

211.89 Rejected components, drug product containers, and closures.

211.94 Drug product containers and closures.

### Subpart F—Production and Process Controls

211.100 Written procedures; deviations.

211.101 Charge-in of components.

211.103 Calculation of yield.

211.105 Equipment identification.

211.110 Sampling and testing of in-process materials and drug products.

211.111 Time limitations on production.

211.113 Control of microbiological contamination.

211.115 Reprocessing.

### Subpart G—Packaging and Labeling Control

211.122 Materials examination and usage criteria.

211.125 Labeling issuance.

211.130 Packaging and labeling operations.

211.132 Tamper-evident packaging requirements for over-the-counter (OTC) human drug products.

211.134 Drug product inspection.

211.137 Expiration dating.

### Subpart H—Holding and Distribution

211.142 Warehousing procedures.

211.150 Distribution procedures.

### Subpart I—Laboratory Controls

211.160 General requirements.

211.165 Testing and release for distribution.

211.166 Stability testing.

211.167 Special testing requirements.

211.170 Reserve samples.

211.173 Laboratory animals.

211.176 Penicillin contamination.

### Subpart J—Records and Reports

211.180 General requirements.

211.182 Equipment cleaning and use log.